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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,834	03/16/2004	Steven M. Ruben	PZ029P1D3	2119

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EXAMINER	
HAMUD, FOZIA M	

ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/800,834	RUBEN ET AL.	
	Examiner	Art Unit	
	Fozia M. Hamud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *1-10, 13-15, 17-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11,12 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/16/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restriction:

1a. Applicant's election with traverse of the invention of Group II (new claims 11, 12 and 15), drawn to an isolated polypeptide, is acknowledged. The traversal is on the grounds that search and examination of Groups II, III, IV, VI and IX does not present undue burden to the Examiner. Applicant reserves the right to request rejoinder of the process claims.

This traversal has been fully considered but is not deemed persuasive. The inventions of Groups II, III, IV, VI and IX are drawn to patentably distinct inventions and are classified in different classes and sub-classes and each distinct subject has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search, (MPEP § 808.02). Also, a single search would not reveal art pertinent to all of the claimed inventions. Thus, searching and examining more than one invention would pose an undue burden on the Examiner. Applicant's right to request rejoinder of the process claims is acknowledged.

The requirement is still deemed proper and is therefore made FINAL.

The elected invention is Group II (claims 11, 12, 16). Therefore, claims 1-10, 13-15, 17-26 are withdrawn from prosecution as being drawn to a non-elected invention.

Information Disclosure Statement:

2a. The information disclosure statements (IDS) submitted on 16 March 2004, has been received and complies with the provisions of 37 CFR §1.97 and §1.98. The

references in the parent application number 10/115,123 have been considered as to the merits.

Specification:

3a. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

3b. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Priority:

4. Based on the information given by Applicants and an inspection of the patent applications, the Examiner has concluded that the subject matter defined in this application is supported by PCT/US99/13418, filed on 15 June 1999, because this application discloses the polypeptide of SEQ ID NO:161, however, none of the provisional applications disclose this polypeptide. Accordingly, the effective filing of the current application is 15 June 1999.

Should the applicant disagree with the examiner's factual determination above, it is incumbent upon the applicant to provide the serial number and specific page number(s) of any parent application filed prior to 06/15/1999, which specifically supports the particular claim limitation for each and every claim limitation in all the pending claims which applicant considers to have been in possession of and fully enabled for prior to 06/15/1999.

Claim Objections:

5a. Claim 16 is objected to because of the following informalities: Claim 16 depends from non-elected claim 15. Appropriate correction is required.

Claim rejections- Non-Obviousness-type Double patenting:

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.
Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5a. Claims 11, 12 and 16 are rejected on the ground of nonstatutory double patenting over claims 1-3, 9, 10 and 13 of U. S. Patent No. 6,475,753, since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

Instant claims 11, 12 and 15 are drawn to an isolated polypeptide that 95% identity to polypeptide of SEQ ID NO:161 or variants of said polypeptide. Claims 1-3, 9, 10 and 13 of U.S. Patent No. 6,475,753 are drawn to the polypeptide of SEQ ID NO:161 or a polypeptide that is at least 90% identical to the polypeptide of SEQ ID NO:161.

However, the claimed polypeptide and the polypeptide of patented claims are of the same scope, since they Both encompass the polypeptide of SEQ ID NO:161 and variants thereof. Therefore, allowance of the pending claims, would have the effect of extending the enforceable life of the allowed claims beyond statutory limit.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6a. Claims 11, 12 and 16 are also rejected under 35 U.S.C. 112, first paragraph. Claims 11, 12 and 15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polypeptide having the amino acid sequence set forth in SEQ ID NO:161, does not reasonably provide enablement for a polypeptide at least 95% identical to the polypeptide of SEQ ID NO:161 or a variant, allelic variant or species homologue of SEQ ID NO:161, or a secreted form of SEQ ID NO:161, wherein the secreted form comprises sequential amino acid deletions from either the C-terminus or the N-terminus. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The instant claims are drawn to variants of the polypeptide of SEQ ID NO:161 without the recitation of a specific biological activity. Therefore, one of ordinary skill in the art would not reasonably predict that a polypeptide less than the full length of SEQ ID NO:161 would retain a desired activity. Furthermore, while recombinant techniques

are available, it is not routine in the art to screen large numbers of polypeptides that might potentially retain a desired activity, because the expectation of obtaining similar activity is unpredictable. Thus one of skill in the art would require additional guidance, such as information as to what structural features would result in variants of the protein of SEQ ID NO:161, which retain the desired activity. Thus, to practice the invention commensurate with the scope of the claims would result in undue experimentation. Thus without information regarding which regions are critical to a specific function, the full scope of the claimed invention is not enabled.

In summary, the amount of experimentation required for one of ordinary skill in the art to use the claimed invention, a polypeptide comprising at least 95% identity to the polypeptide fragment of SEQ ID NO:161 or the encoded sequence included in ATCC Deposit No:209782, or to a polypeptide domain of SEQ ID NO:161, or a variant, allelic variant or species homologue of SEQ ID NO:161, or a secreted form pf SEQ ID NO:161, wherein the secreted form comprise sequential amino acid deletions from whether the C-terminus or the N-terminus, would be undue. In Ex parte Forman, 230 USPQ 546 (Bd. Pat. Appls, and Interf. 1986), the Board considered the issue of enablement in molecular biology. The Board held that the following factors should be considered to determine whether the claimed invention would require of the skilled artisan undue experimentation: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the

breadth of the claims. The level of skill in the art of molecular biology is high, but the nature of the invention is not well characterized (i.e. the polypeptide of SEQ ID NO:161 of the instant invention is novel). Therefore, since the state of the prior art is relatively silent to the invention that is claimed, and since Applicants have not provided which regions of the polypeptide are critical for its' function, or any disorders that involve said protein, the skilled artisan would not know how to make and use the claimed polypeptide.

6b. Claims 11-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The claims are drawn to polypeptides having at least 95%, sequence identity or variants, allelic variants, species homologues of a particular disclosed sequence. The claims do not require that the polypeptide possess any particular biological activity, nor any particular conserved structure, or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of polypeptides that is defined only by sequence identity.

To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor

present in the claim is a partial structure in the form of a recitation of percent identity. There is not even identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See Fiers v. Revel, 25 USPQ2d 1601 at 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.
One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481 at 1483. In Fiddes, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only isolated polypeptides comprising the amino acid sequence set forth in SEQ ID NO:161 or an isolated polypeptide encoded by sequence included in ATCC Deposit No:209782, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph.

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

6c. Claims 11-12 are ejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 11-12 are rejected, because the claims are drawn to an isolated polypeptide encoded by sequence included in ATCC accession number 209782. The specification discloses that HCEJQ69 cDNA corresponds to ATCC accession number 209782, (see table on page 219). Thus it is apparent that the cDNA is required to practice the claimed invention. As such said cDNA must be readily available or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If the cDNA is not so obtainable or available, the requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of this cDNA.

The specification, provides an ATCC accession number for the claimed cDNA, however, the specification lacks complete deposit information for the deposit of the

cDNA. If a deposit was made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the instant invention will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. If a deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809 and MPEP 2402-2411.05, Applicant may provide assurance of compliance by affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that (a) during pendency of the application, access to the invention will be afforded to the Commissioner upon request, (b) all restrictions upon availability to the public will be irrevocable removed upon granting of the patent, © the deposit will be maintained in a public depository for a period of 30 years, or 5 years after the last request or for the enforceable life of the patent, whichever is longer, (d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807) and (e) the deposit will be replaced if it should ever become inviable.

Claim rejections-35 USC § 112, second paragraph:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 11 and 12 are rejected under 35 U.S.C. 1 12, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4b. Claim 11 recites "...having biological activity...", however, it is unclear which biological activity is being referred to. The metes and bounds of the claim cannot be ascertained.

Claims 12 is rejected under 35 U.S.C. 112, second paragraph, as far as they depend from claims 11, for the limitations set forth directly above.

Conclusion:

8. No claim is allowed.

Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M. Hamud whose telephone number is (571) 272-0884. The examiner can normally be reached on Monday, Thursday-Friday, 6:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-00835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Fozia Hamud
Patent Examiner
Art Unit 1647
28 June 2007

Eileen B. O'Hara

EILEEN B. O'HARA
PRIMARY EXAMINER